GP/1642

PATENT
242/026
(DIV 3 OF '682)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Neil H. Bander

Serial No.: Not yet assigned

Filing Date: Herewith

(Divisional of Serial No. 08/838,682 Filed on April 9, 1997)

For: TREATMENT AND DIAGNOSIS OF PROSTATE CANCER

Group Art: 1642

#2/2

Examiner: Y. Eyler

PETITION TO MAKE SPECIAL UNDER 37 C.F.R. §1.102 BASED ON RELATION TO CANCER

Assistant Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Sir:

Applicant hereby petitions, pursuant to 37 C.F.R. § 1.102 and M.P.E.P. § 708.02, to make the above-identified application special and thereby advance examination of the application, due to the relation of the application to cancer.

CERTIFICATE OF MAILING
(37 C.F.R. §1.10)

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as 'Express Mail Post Office To Addressee' in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

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Felicia Reyes
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Felicia Reyes
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LA-100082.1

The invention relates to methods for the treatment and diagnosis of prostate cancer with biological agents, including antibodies or binding portions thereof. Prostate cancer is the most common cancer in men, and is the second leading cause of death in men who die from neoplasia. (Specification, page 1, lines 16-21.) Current methods for the detection and treatment of prostate cancer suffer from significant deficiencies. (Specification, page 1, line 24 to page 4, line 30.) Specifically, with respect to prostate cancer detection, imaging methods, such as computed tomography or magnetic resonance, are unable to detect tumors having a volume below about 1 cm. Furthermore, these methods are non-specific in that they are unable to specifically identify imaged masses as tumors. Other conventional methods rely on the detection of elevated levels of serum acid phosphatase. However, these methods also are non-specific and subject to false positive readings, due to the presence of phosphatase isoenzymes that are not correlated with disease.

With respect to methods to treat prostate cancer, current methods include surgical intervention and radio- or chemotherapy. (Specification, page 4, line 33 to page 6, line 27.) However, surgical intervention often does not guarantee removal of all cancerous cells, and prostate cancer has proven to be resistant to chemotherapy. Radiation therapy has significant side effects, and requires supplementation with hormones and other drugs that themselves induce side effects.

Current methods to detect and/or treat prostate cancer using monoclonal antibodies have met with limited success. Some antibodies cannot distinguish between normal and cancerous prostate cells. (Specification, page 7, line 26 to page 8, line 2.) As a result, detection and treatment are non-specific. Other antibodies are specific to malignant prostatic tissue, but can

only detect dead cancerous cells. (Specification, page 8, line 34 to page 9, line 21.) As a result, living, viable cancer cells cannot be detected or treated.

The present invention relates to methods for detecting and treating prostate cancer, using biological agents, including antibodies, directed against the extracellular domain of prostate-specific membrane antigen ("PSMA"). The biological agents and antibody recognize antigens which are exposed on the surface of living prostate epithelial cells, including cancerous prostate epithelial cells. (Specification, page 11, line 21 to page 12, line 2.) As a result, living cancerous epithelial prostate cells can be targeted by the binding agents and antibody of the present invention for detection and killing or ablation of the cancerous cells. The specification describes methods to accomplish such detection and killing or ablation. (Specification, page 13, line 9 to page 17, line 4.)

The claims now pending specifically point out and claim the use of biological agents, including antibodies, directed against the extracellular domain of PSMA in the detection of cancer. See Claims 24-42. The relationship of the application to cancer is thus indisputable.

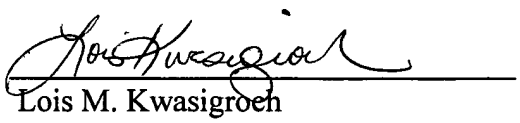
The appropriate filing fee of $130.00, as per 37 C.F.R. §1.17(i), is included herewith.

No additional fee is believed due at this time. The Examiner is authorized to charge any additional fee due or refund any overpayment to **Deposit Account No. 12-2475**. If a telephone conference would, in any way, facilitate prosecution of the application, the Examiner is encouraged to contact the undersigned.

Respectfully submitted,

LYON & LYON LLP

Dated: July 20, 1999

By: 
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